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5.0 510(k) Summary

As required by 21 CFR 807.87(h), a 510(k) Summary for this Premarket Notification submission is provided below. A 510(k) statement is therefore not required.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PHILIPS

Philips Defibrillator Monitor

Submitter's Name and Address

Submitter's Name:	Philips Medical Systems
Division:	Emergency Care Solutions
Address:	3000 Minuteman Road
City, State, and Zip:	Andover, MA 01810
Contact Name:	Paul Schrader, Senior Regulatory Affairs Manager
Telephone / Fax:	(978) 659-2404 / 978-659-3610
510(k) Summary Date	October 28, 2011

Manufacturers' Information: Establishment Registration Number

Establishment name:	Philips Medical Systems
Address:	3000 Minuteman Road
	Andover, MA 01810
Establishment Registration No.	1218950

Device Details:

Proprietary or Trade Name:	HeartStart XL +
Common Name:	ALS Defibrillator Monitor
Device Class:	III for AED mode (MKJ), II for the remaining applicable ProCodes / CFR classifications
Device ProCodes:	MKJ, LDD, DRO, DQA, DXN
Device CFR:	Several see table below
Classification Panel:	Cardiovascular
21 CFR Classification Name / Description	Several see table below

Classification	ProCode	Classification Description
870.5310-III	MKJ	Defibrillators, Automatic, External
870.5300-II	LDD	Low-energy defibrillator [1]
870.5550-II	DRO	External Transcutaneous Pacemaker (Non-invasive)
870.2700-II	DQA	Pulse Oximeter
870.1130-II	DXN	Non-Invasive Blood Pressure
870.1025-II	MHX	Arrhythmia detector and alarm

Device Name: **Philips XL+ Defibrillator Monitor**

Intended Use: The HeartStart XL + is intended for use in a hospital setting by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced life support, or defibrillation. It must be used by or on the order of a physician.

When operating as a semi-automatic external defibrillator in AED Mode, the HeartStart XL+ is suitable for use by medical personnel trained in basic life support that includes use of an AED.

When operating in Monitor, Manual Defib or Pacer Mode, the HeartStart XL+ is suitable for use by healthcare professionals trained in advanced life support.

Indications for Use: The HeartStart XL+ is a defibrillator monitor. The device is for use by qualified medical personnel trained in the operation of the device and certified by training n basic life support, advanced life support or defibrillation. It must be used by or on the order of a physician.

AED Therapy: AED Mode is used in the presence of a suspected cardiac arrest on patients that are unresponsive, not breathing and pulseless.

Manual Defibrillation: Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive.

Synchronous defibrillation (cardioversion) is indicated for termination of atrial fibrillation.

Non-Invasive External Pacing: The pacing option is indicated for treating patients with symptomatic bradycardia.

Pulse Oximetry: The SpO2 option is indicated for use when it is beneficial to assess the patient's oxygen saturation level.

Non-invasive Blood Pressure Monitoring: The NBP option is indicated for non-invasive measurement of a patient's arterial blood pressure.

ECG Monitoring: The ECG monitoring option is indicated to be used for monitoring, alarming, and recording of the patient's heart rate and morphology.

Device Description

The HeartStart XL+ is a lightweight, portable defibrillator/monitor. It provides four clinical modes of operation: Monitor, Manual Defibrillator, AED and Pacer (optional).

In Monitor Mode, depending on the ECG inputs being used (pads, paddles, ECG cable), you can monitor up to 3 different ECG waveforms at one time. Using a 3-lead ECG cable you can view Lead I, II or III. With a 5-Lead ECG cable, you can view two leads from Leads I, II, III, avR, avL, avF or V. Optional monitoring of SpO2 or NBP is available using existing and previously cleared technology as references in the predicate device comparison of the summary. Measurements are presented on the display and alarms are available to alert you to a change in the patient's condition. You can also display the Vital Signs Trending Report to view all key parameters and their measurements at a glance.

Manual Defibrillation Mode provides simple 1-2-3 defibrillation. You analyze the patient's ECG and, if appropriate: 1) select an energy setting; 2) charge; and 3) deliver the shock. Defibrillation is performed using paddles (internal or external) or multifunction electrode pads. You can also perform synchronized cardioversion in Manual Defibrillation Mode. The HeartStart XL+ incorporates Philips' low energy SMART Biphasic waveform for defibrillation which has been in use for over a decade.

In AED Mode, the HeartStart XL+ analyzes the patient's ECG and determines whether a shock is advised. Voice prompts guide you through the 2-step defibrillation process, with easy-to-follow instruction and patient information. Voice prompts are reinforced by messages on the display.

Optional Pacer Mode offers non-invasive transcutaneous pacing therapy. Pace pulses are delivered through multifunction electrode pads.

Predicate Device Comparison: Previous Philips Defibrillator Monitors

	Specification / Clinical Function	HeartStart XL HeartStart MRx	Philips HeartStart XL+ Complies w/ IEC 60601-2-4:2005 & monitoring standards listed below	Comparison	Predicate 510(k) #s
THERAPY	Defibrillation Waveform	Bi-phasic 1 – 200 Joules	Bi-phasic 1 – 200 Joules	Same design as HeartStart XL and HeartStart MRx	K001725 HeartStart XL K031187 HeartStart MRx
	Defibrillation Modes	Manual and AED	Manual and AED		K001725 HeartStart XL K031187 HeartStart MRx
	AED Modes	Adults	Adults and Pediatrics	Pediatrics has been added by using previously reviewed algorithm and pads	K001725 HeartStart XL (Adult) K031187 HeartStart MRx (Adult) K003819 FR2 (Pediatrics)
	Shock Advisory Algorithm	Hewlett-Packard Shock Advisory	HeartStream Patient Analysis System (PAS) Algorithm	Philips has standardized on use of the PAS algorithm.	K954597 HP Shock Advisory (Adult) K955628 PAS Algorithm (Adult) K003819 PAS Algorithm (Pediatrics)
	Cardioversion	Available	Available	Same waveform as MRx	K010634 Cardioversion added to XL K031187 HeartStart MRx
	External Pacing	Yes w/ Pads	Yes w/ Pads	Same waveform as MRx	K001725 HeartStart XL K031187 HeartStart MRx

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	Specification / Clinical Function	HeartStart XL HeartStart MRx	Philips HeartStart XL+ Complies w/ IEC 60601-2-4:2005 & monitoring standards listed below	Comparison	Predicate 510(k) #s
Pads and Paddles	Pads	Several different pads as listed in predicate list in the last column	No change in pad construction from pads currently used with HeartStart XL/MRx Complies w/ IEC 60601-2-4:2005	Same pads as currently being used with HeartStart MRx and HeartStart XL. Labeling changed to standardize format and content for whole family. One IFU created for three different groupings: infant pads (previously called pediatric pads), adult pads and adult preconnect pads.	Infant Pads: M3504A:K992977 M3717A:K003228 M3719A (Radiotransparent): K0012218 Adult / Child Pads: M3501A: K991871 M3713A: K002806 M3716A (Radiolucent): K002806 M3718A (Radiotransparent): K002806 989803166021(Preconnect): K002806
	Paddles	Internal and External	Complies w/ IEC 60601-2-4:2005	No change to internal paddles. External paddles were modified to allow use of inter-changeable electrode selected on patient size. Customer no longer needs two separate external paddles.	K021453 Internal Paddles K001725 External Paddles
MONITORING	ECG monitoring	Tested to 60601-2-27	Complies w/ IEC 60601-2-27: 2005	Available on both XL and MRx, design is leveraged from MRx	K031187 HeartStart MRx
	SPO2 monitoring	Tested to ISO 9919	Complies w/ ISO 9919:2005	Available on both XL and MRx, acquisition and processing of SPO2 data has not changed from MRx	K031187 HeartStart MRx
	NBP monitoring	Tested to 60601-2-30 on MRx, Not available w/ XL	Complies w/ IEC 60601-2-30: 1999	acquisition and processing of SPO2 data has not changed from MRx	K031187 HeartStart MRx

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Performance Data

The HeartStart XL + has all of the major features of the HeartStart XL plus the additional feature of NBP monitoring. Testing for performance was done according to applicable FDA recognized consensus standards for electrical defibrillation, ECG monitoring, SPO2 monitoring, and NBP monitoring. Additional standards testing beyond the list of FDA recognized standards was also performed. Small feature changes have been made to align the design with the 2010 AHA Resuscitation Guidelines. The previous product had only been evaluated against the 2005 AHA guidelines.

Conclusions

The HeartStart XL + is substantially equivalent to previous Philips defibrillator monitor products and accessories. The predicates HeartStart FR2, HeartStart XL, HeartStart MRx have been commercially distributed and successfully used for several years.

Product design and testing was done in conformance with FDA-recognized standards. Conformance with recognized standards ensures product design and function will address known issues related to safety and effectiveness.

Based on similarity in technology, characteristics and indications for use as the predicate, the Philips defibrillator monitors (new and predicate) described in this summary are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 16 2012

Philips Healthcare
c/o Mr. Paul Schrader
Senior Regulatory Affairs Manager
3000 Minuteman Road
Andover, MA 01810

Re: K110825
Trade/Device Name: Philips Heartstart XL+, Philips External Paddles, Philips Multifunction Electrodes
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External defibrillator
Regulatory Class: Class III
Product Code: MKJ, LDD, DRO, DQA, DXN, MHX
Dated: February 3, 2012
Received: February 6, 2012

Dear Mr. Schrader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

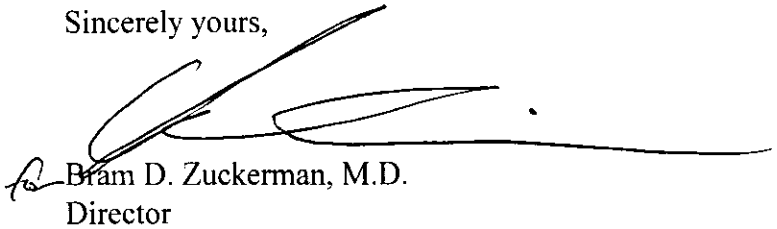
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number: _____

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ECG Monitoring

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Prescription Use (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110825